

Remarks

Claims 1, 2, 6 to 9 and 11 to 17 are pending in this application of which claims 1, 2 and 17 are in independent form. Claim 17 is new. Support for this new claim can, for example, be found in Example 5.

35 USC §112, first paragraph rejection

In paragraphs 2 to 4 on pages 2 to 4, the Office rejected claims 11 to 14 as non-enabled under 35 USC §112, first paragraph.

While the Office acknowledged that the specification is enabling for the treatment of tumors (see, e.g., claims 15 and 16), the Office expressed the opinion that the specification is not enabling for the prophylaxis, therapy, follow-up and aftercare of diseases associated with cell- growth, cell differentiation and/or cell division in general.

The Office refers to the “Wands” factors to be considered in the context of an enabling rejection:

- 1.) Breath of the claim;
- 2.) Nature of the invention;
- 3.) State of the prior art;
- 4.) Level of ordinary skill in the art;
- 5.) Level of predictability in the art;
- 6.) Amount of direction and guidance provided by the inventor;
- 7.) Existence of working examples;
- 8.) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The Office acknowledged that the level of ordinary skill in the art is high (4), but expressed the opinion that this skill is limited to the preparation and use of anti-tumor Pt(IV) complexes.

The Office further expressed the opinion that the predictability (5) is very low and that thus there

is a need for higher levels of directions and guidance by applicant. The Office in particular noted that using anti-tumor data to extrapolate to the use in therapies other than cancer is not proper. The Office expressed the opinion that the mode of action against tumors would not necessarily be the same against such other diseases (here: therapy, follow-up and aftercare of diseases associated with cell- growth, cell differentiation and/or cell division). Finally, the Office also expressed the opinion that the specification fails to provide evidence of prophylaxis.

The Office concluded that the quantity of experimentation required to use the compounds as claimed, based on the applicant's disclosure would cause an undue burden since the person of ordinary skill in the art would have to perform a significant amount of experimentation to ascertain how to use the claimed compounds in therapies other than cancer.

Applicant submits that the Office has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement, unless there is a reason to doubt the objective truth of applicant's statements. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). References should be supplied if possible to support a *prima facie* case of lack of enablement, but are not always required. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). However, specific technical reasons are always required [MPEP §2164.04]. Applicant submits his belief that specific technical reasons have not been provided.

Applicant notes that tumor diseases are always associated with abnormalities in cell growth, cell differentiation or cell division. Thus, tumor cells do indeed provide a valid model for diseases associated with cell- growth, cell differentiation and/or cell division. Diseases associated with cell- growth, cell differentiation and/or cell division form a group of related disorders, which are treated with similar medications. Thus, considering the knowledge and ample working examples conveyed by the specification, an extrapolation to these related disorders does indeed become quite possible and predictable.

As a result, a person skilled in the art would be able, without undue experimentation, to transfer the use of the claimed compound to such diseases.

Equally, a person skilled in the art, e.g., a medical scientist or a physician, is used to and well versed in adjusting the dose and way of administration of a certain compound. Especially oncologists are familiar with off-label use of medication. Particularly, such a person knows that the use in prophylaxis depends strongly on the medical history of the patient and his/her family. Accordingly, the physician always has to adjust the dose to the specific needs of each patient.

A patent need not teach, and preferably omits, what is well known in the art. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). It is also well settled that the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985) (MPEP §2164.01). In the instant case, the adaptations described above are well within the typical range that a medical researcher and practitioner has become accustomed to.

Applicant would also like emphasize that the disclosure provides a wide array of working examples as shown by the growth inhibition tests on a host of human cell lines (Tables 1 to 5, examples 5 to 7) and would like to refer to Office to MPEP §2164.02.

35 USC §112, second paragraph rejection

On pages 4 and 5, paragraphs 5 and 6, the Office rejected claims 1, 2, 6 to 9, 15 and 16 under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, with regard to claim 1, the Office expresses its belief that the recited process does not produce *trans*- or *cis*-diammoniumdichlorodihydroxoplatinum (IV) but rather a derivative of said compound.

With regard to claim 2, it is not clear to the Office how the general formula in claim 2 can be a

neutral compound when X_1 and X_2 is either calcium or magnesium ions.

Applicant notes, that the highest U.S. Patent Court, the CAFC, repeatedly stated, including in June of last year (*Young v. Lumenis*, 06-1455, Fed. Cir., June 27, 2007), that claims are indefinite only when they are “not amenable to construction or are insolubly ambiguous.” Also, the CAFC made clear that examination of any intrinsic evidence is required in an indefiniteness determination.

Similarly, the Manual of Patent Examining Procedure (MPEP) clarifies that all that is required for a particular phrase to be definite is a reasonable degree of clarity and particularity. The MPEP also emphasizes that the definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by those possessing the ordinary level of skill in the pertinent art at the time the invention was made (MPEP §2173.02). The MPEP refers to *Metabolite Labs.* in which the CAFC stated that only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366 (Fed. Cir. 2004).

Applicant submits that the present claims, in particular, when viewed in conjunction with the disclosure, readily meet the threshold requirement of clarity and particularity.

With regard to claim 1, applicant submits that the process can lead to both, *trans*- or *cis*-diammoniumdichlorodihydroxoplatinum (IV) and derivatives thereof. Different derivatives result from the use of different minerals acids or alkaline solutions.

The Office is respectfully directed to Example 1 of the description which shows the synthesis of *trans*- or *cis*-diammoniumdichlorodihydroxoplatinum (IV) according to the method of claim 1. In this context, applicant would like to direct the Office's attention to the fact that “cisplatin” as used in this Example is a short for *cis*- diammoniumdichlorodihydroxoplatinum (II). Thus, in particular in view of the disclosure, claim 1 readily meets the threshold requirements of clarity and precision.

With regard to claim 2, applicant observes that there is no indication in the description that the shown compound should be neutral. While there is no charge indicated in the formula, the

person skilled in the art is well aware of the fact that a respective charge arises due to changes in positions X_1 and X_2 . This person will readily know which charge the compound bears for each possible X_1 and X_2 .

In view of the above, reconsideration of the rejections is respectfully requested. Applicant believes that all issues raised by the Office Action of May 14, 2008 should be addressed to the satisfaction of the Office. However, the undersigned urges the Office to call her at the number provided below so that any issues or concerns can be promptly addressed and/or clarified. Otherwise, an early notice of allowance is respectfully requested.

No fees are believed to be due. However, the Commissioner is authorized to charge undersigned's deposit account for any fees that may be required in connection with this filing.

Respectfully submitted,

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